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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/630,215	08/01/2000	John F. O'Connor	54205-A-PCT-US/JPW/SHS/MV	7218

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John P White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
GABEL, GAILENE	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/630,215	O'CONNOR ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's response filed 4/26/04 is acknowledged and has been entered. Claims 58-67 are pending and remain under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 103

2. In light of Applicant's argument, the rejection of claim 62 under 35 U.S.C. 103(a) as being unpatentable over Penfold et al. (US 6,133,048) in view of Morton et al. (WO/ 88/04779, Abstract), is hereby, withdrawn.

3. In light of Applicant's argument, the rejection of claims 58-61, 63, and 65-67 under 35 U.S.C. 103(a) as being unpatentable over Penfold et al. (US 6,133,048) in view of Morton et al. (WO/ 88/04779, Abstract), and in further view of Birken et al. (Endocrinology, 1993), is hereby, withdrawn.

Rejections Maintained

Double Patenting

4. Claims 58-67 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53, 59, 60, 65, 71, 72, and 77-82 of copending Application No. 09/017, 976, now US Patent 6,500,627, for reasons of record.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The instant claims are drawn to a method for predicting pregnancy outcome in a subject using a monoclonal or polyclonal antibody to bind to an early pregnancy-associated molecular isoform of hCG (EPMI-hCG). The monoclonal or polyclonal antibody is described in the specification as being generated by a well-characterized antigen, C5-hCG, and as being able to bind to an epitope present in EPMI-hCG. EPMI-hCG, is likewise, said to be recognized by a monoclonal antibody, B-152 which is deposited with the American Type Culture Collection under Designation No. HB-12467. However, since the recitation "which isoform is recognized by the B152 antibody deposited with the American Type Culture Collection under Designation No. HB-12467" does not partake in the actual method steps of the claim, such recitation bears no patentable weight. Additionally, it is proper for purposes of this rejection to interpret "early pregnancy associated molecular isoform of hCG" as "hyperglycosylated isoform of gonadotropin" observed in early pregnancy of

subjects in Down's Syndrome cases, absent a definitive and distinctive characterization of this hCG isoform, because unpatented claims are given the broadest interpretation consistent with the specification.

5. Claim 62 and 67 is rejected under 35 U.S.C. 102(e) as being anticipated by Cole et al. (US Patent 6,429,018).

Cole et al. disclose a method for determining the amount of an early pregnancy-associated molecular isoform of hCG or EPMI-hCG (prenatal screening for nicked hyperglycosylated gonadotropin in Down's Syndrome cases) in a urine sample. In an immunometric assay, Cole et al. teach contacting a sample from the subject with a first capture antibody, B152, which binds EPMI-hCG or hyperglycosylated gonadotropin, which is recognized by the B152 antibody. Thereafter, the sample is contacted with a second labeled antibody to hCG, β-core fragment of hCG, α-subunit, and/or a β-subunit, which also binds to EPMI-hCG simultaneously with the first antibody, and the sample is measured for the amount of bound second antibody in the sample. Cole et al. disclose that the B152 antibody recognizes nicked hyperglycosylated hCG obtained from choriocarcinoma patients. The urine sample is obtained from the subject in her first trimester, within about the first 9 weeks to 13 weeks of pregnancy (see column 5, lines 14-18, 42-67, column 6, lines 38-54, and Example 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 58-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole et al. (US Patent 6,429,018) in view of Birken et al. (Endocrinology, 1993).

Cole et al. has been discussed supra. Cole et al. differ from the instant invention in failing to teach contacting a second portion of the sample with a third capture antibody which binds to intact non-nicked hCG, then a fourth labeled antibody which binds to the intact non-nicked hCG simultaneously with the third antibody.

Birken et al. teach a two-site immunoradiometric assay used to evaluate early pregnancy losses by separating nicked from intact non-nicked hCG as well as from the β-core fragment (see page 390). In addition to first two antibodies, Birken et al. teach using a third capture antibody (B109) that specifically binds INN HcG (intact HcG heterodimer) and a fourth labeled (tracer) antibody (B108) that likewise, specifically binds INN HcG. (See page 1391, column 1). The ratios of intact hCG, nicked hCG, and also hCG β-core fragment are determined.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to further incorporate monoclonal antibodies in the immunometric assay method as taught by Cole with the method taught by Birken

because Birken specifically taught that use of two-site immunometric assay that separates hCG forms provides advantage in monitoring different complex hCG functions.

7. Claims 63-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole et al. (US Patent 6,429,018) in view of Birken et al. (Endocrinology, 1993) and in further view of Foster et al. (US Patent 4,444,879).

Cole et al. and Birken et al. have been discussed supra. Cole et al. and Birken et al. differ from the instant invention in failing to incorporate the antibodies and reagents into a kit format. Cole et al. and Birken et al. further differ in failing to teach B207 deposited with the ATCC under PTA- 1626.

Foster et al. teaches incorporating labels, antibodies, and reagents into a kit format.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the reagents, labels, and antibodies taught by Cole and Birken into a kit arrangement as taught by Foster because test kits are conventional and well known in the art for their recognized advantages of convenience and economy. Additionally, the B207 antibody constitutes an obvious variation of antibodies used to bind hCG, β-core fragment of hCG, α-subunit, and/or a β-subunit which also binds hyperglycosylated gonadotropin, and which is routinely varied in the pregnancy immunometric assay art.

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641

Gailene R. Gabel
Patent Examiner
Art Unit 1641
June 29, 2004